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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35,37 and 47-55* is/are pending in the application.

4a) Of the above claim(s) *48 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-35,37,47,50 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the surface capillary fiber having a channel along its outer side that extends substantially parallel to the length of the surface capillary fiber.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-35, 37, 47, 49, 50, and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, the use of “the surface capillary fiber” in lines 3-8 and the use of “the fiber" in line 4 are unclear as a plurality of surface capillary fibers have been recited in lines 1-2 and it is unclear which surface capillary fiber is being recited with respect to a quantity of bioactive agent being associated with the surface capillary fiber. In claim 27, the use of “the surface capillary fibers” in line 2 is unclear as to whether this refers to the plurality of surface capillary fibers which have been recited in lines 1-2 of claim 20 or if this refers to the “additional surface capillary fibers” recited in line 2 of claim 27.

Similarly, in lines 5-7 of claim 28, in line 4-6 of claim 34, in lines 6-8 of claim 47 in line 2 of claim 49, and in line 1 of claim 50, it is unclear which one of the plurality of surface capillary fibers is being referred to by the use of "the surface capillary fiber". Also, in line 9 of claim 47, the use of "the channels of the fibers" is in error as a surface capillary fiber having a channel has been recited and, thus, there is no recitation of more than one channel.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 20-22, 24-35, 37, 47, 49, 50, 52, 54, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by DiCarlo et al (U.S. Patent No. 6,929,626). DiCarlo et al disclose a medical device (10, 40) comprising a plurality of surface capillary fibers associated with at least a portion of a surface of the device (lines 35-50 of column 5). The fibers comprise a polymer and a quantity of bioactive agent associated with the surface capillary fiber (lines 14-57 of column 11 and lines 1-63 of column 13). In lines 46-52 of column 2 and in lines 20-23 of column 13, DiCarlo et al disclose the fibers releasably containing a bioactive agent and disclose that the

bioactive agents may be used to target therapeutic agents to specific locations in the body and, thus, the bioactive agent is seen to be able to elute in a controlled way from the fiber or fibers when the surface capillary fiber (or fibers) is contacted by a patient's body fluids or tissue. As seen in Figure 9, the surface capillary fiber (or fibers) has a channel along its outer surface that extends substantially parallel to the length of the surface capillary fiber where the channel extends along at least a portion of the length of the surface capillary fiber. In lines 22-34 of column 5, DiCarlo et al disclose that the medical device is a percutaneous device or an implantable device. As to claims 21, 22, and 24, see lines 32-44 of column 13. As to claim 25, the surface capillary fiber is considered to have a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter. The device is configured for placement within a blood vessel without blocking flow through the vessel. As to claim 27, the device comprises a catheter (40) and additional surface capillary fibers (44) where the surface capillary fibers (42) are associated with the inner surface of the catheter. As to claim 28, DiCarlo et al disclose a tubular medical device (10, 40) having a tubular substrate with an interior surface and an exterior surface where a plurality of surface capillary fibers are associated with at least a portion of one of the surfaces with an adhesive, mechanical binding, heat bonding, or chemical bonding (lines 9-0 of column 7) and where the surface capillary fiber (or fibers) has a channel along its outer surface that extends substantially parallel to the length of the surface capillary fiber where the channel extends along at least a portion of the length of the surface capillary fiber. The tubular medical device is a catheter or a microcatheter. The surface capillary

fibers are associated with a bioactive agent (lines 1-63 of column 13). As to claim 32, see lines 32-37 of column 13. As to claim 33, at least one of the surface capillary fibers is associated with at least a portion of the interior surface. As to claim 34, DiCarlo et al disclose an implantable medical device comprising a non-porous surface (44), at least a portion of which is covered with surface capillary fibers (42) and where the surface is contoured to match a portion of a structure within a patient and where the surface capillary fiber (or fibers) has a channel along its outer surface that extends substantially parallel to the length of the surface capillary fiber where the channel extends along at least a portion of the length of the surface capillary fiber. As to claim 35, see lines 45-48 of column 7. As to claim 37, see lines 1-63 of column 13. As to claim 47, DiCarlo et al disclose a method for delivering a bioactive agent using a percutaneous or implantable medical device (40, 120, 140) where a patient's body fluids/tissues contact a plurality of surface capillary fibers associated with at least a portion of a surface of the device (Figures 6, 19, 26) and where the surface capillary fiber (or fibers) has a channel along its outer surface that extends substantially parallel to the length of the surface capillary fiber where the channel extends along at least a portion of the length of the surface capillary fiber. The channels of the fibers are associated with a bioactive agent (lines 1-63 of column 13) that elutes in a controlled way from the fibers. As to claim 49, contacting of the patient's fluids or tissue comprises delivery of a catheter (40, 120, 140) associated with the surface capillary fiber. As to claim 50, see Figure 6. As to claim 52, see lines 32-44 of column 13. As to claims 54 and 55, see lines 9-0 of column 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiCarlo et al in view of Samson et al (U.S. Patent No. 6,066,149). DiCarlo et al disclose the device substantially as claimed. Even though DiCarlo et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), DiCarlo et al are silent as to the specifics of the bioactive agent comprising tissue plasminogen activator (tPA). Samson et al disclose using a medical device or catheter to deliver bioactive agents such as tPA or urokinase (lines 19-27 of column 5) which are thrombolytic agents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of DiCarlo et al a thrombolytic agent such as tPA as taught by Samson et al as both DiCarlo et al and Samson et al disclose medical device for delivering a bioactive agent such as a thrombolytic agent and Samson et al teach that it is well known to use a thrombolytic agent such as tPA for the bioactive agent which is being delivered into the patient's body.

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiCarlo et al in view of Bucay-Couto et al (U.S. Patent Application Publication No. 2003/0018306). DiCarlo et al disclose the device substantially as claimed. Even though DiCarlo et al disclose a bioactive agent associated with the surface capillary

fiber(s) where the fiber releasably contains the bioactive agent, DiCarlo et al are silent as to the specifics of the bioactive agent being associated with a controlled release agent. Bucay-Couto et al disclose using a medical device or catheter to deliver bioactive agents and teach associating the bioactive agent with a controlled release agent in order to control the release of the bioactive agent (paragraph [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to associate the bioactive agent of DiCarlo et al with a controlled release agent as taught by Bucay-Couto et al as both DiCarlo et al and Bucay-Couto et al disclose medical device for delivering a bioactive agent and Bucay-Couto et al teach that it is well known to use a controlled release agent with the bioactive agent in order to extend the release time of the bioactive agent.

Response to Arguments

9. Applicant's arguments filed April 29, 2009 have been fully considered but they are not persuasive. Applicant's arguments in line 12 of page 7 to line 24 of page 8 are not persuasive as to supporting the disclosure in the specification of the surface capillary fiber having a channel along its outer side that extends substantially parallel to the length of the surface capillary fiber. Specifically, there is no disclosure of a channel along the outer surface of the surface capillary fiber. The channel as only been disclosed as being formed within the surface of the surface capillary fiber (line 25-26 of page 6) or along the surface of the fiber (lines 26-27 of column 11). Also, there is no disclosure of the channel extending substantially parallel to the length of the surface

capillary fiber as there is no mention of “substantially parallel" in the specification. Furthermore, the lack of disclosure of “substantially parallel” is apparent as the specification lacks mention of what constitutes the channel being substantially parallel.

10. Applicant's arguments with respect to claims 20-35, 37, 47, 50, and 52-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-

3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
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